



QUICK ACCESS GUIDE

Understanding **patient access, coverage,** **and support resources** for MODEYSO

This MODEYSO Quick Access Guide provides an overview of MODEYSO, your support team, and how to start patients on MODEYSO with JazzCares support.

INDICATION

MODEYSO is indicated for the treatment of adult and pediatric patients 1 year of age and older with diffuse midline glioma harboring an H3 K27M mutation with progressive disease following prior therapy.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hypersensitivity

MODEYSO can cause severe hypersensitivity reactions.

In the pooled safety population, Grade 3 hypersensitivity reactions occurred in 0.3% of patients receiving MODEYSO. Signs and symptoms of hypersensitivity may include rash, hives, fever, low blood pressure, wheezing, or swelling of the face or throat.

Please see additional Important Safety Information throughout, and full Prescribing Information.

About MODEYSO

MODEYSO is the **first and only FDA-approved treatment** for H3 K27M–mutant diffuse midline glioma in patients with progressive disease following prior therapy.¹

HOW SUPPLIED, STORAGE, AND HANDLING¹

STRENGTH

125 mg

DESCRIPTION

White, opaque, hard capsules printed with “DDP” and “125” on the body and “CMRX” on the cap of the capsule

PACKAGE CONFIGURATION

Each bottle contains 10 capsules and desiccant with a child-resistant closure

NDC NUMBER^a

68727-250-01

68727-0250-01

Store at 20°C to 25°C (68°F to 77°F); excursions permitted from 15°C to 30°C (59°F to 86°F).

^aPayers may require a 10-digit or 11-digit NDC. Both are provided for your convenience.



DOSING AND ADMINISTRATION¹

ONCE-WEEKLY DOSING

MODEYSO is a capsule taken once a week, with a recommended dose of 625 mg (five 125-mg capsules) for patients weighing ≥ 52.5 kg (≥ 115.7 lb).

- For pediatric patients weighing < 52.5 kg, the dose is scaled by body weight. Please see table at right

ORAL ADMINISTRATION

- MODEYSO should be taken on an empty stomach, at least 1 hour prior to or 3 hours after a meal
- The prescribed dose of MODEYSO should be taken at the same time and on the same day each week

See next page for additional dosing information.

Recommended weight-based dosing in pediatric patients (once weekly)

Weight	MODEYSO capsule (125 mg)
10 kg to < 12.5 kg	125 mg (1 capsule)
12.5 kg to < 27.5 kg	250 mg (2 capsules)
27.5 kg to < 42.5 kg	375 mg (3 capsules)
42.5 kg to < 52.5 kg	500 mg (4 capsules)
52.5 kg and above	625 mg (5 capsules)

For patients unable to swallow capsules, the capsule contents may be dissolved in approximately 15 mL to 30 mL of liquid (sports drink, apple juice, lemonade, or water) before administration^a

FDA=Food and Drug Administration; H3=histone 3; K=lysine; M=methionine; NDC=National Drug Code.

IMPORTANT SAFETY INFORMATION (CONT.)

WARNINGS AND PRECAUTIONS (CONT.)

Hypersensitivity (cont.)

Inform patients about the signs and symptoms of hypersensitivity reactions and instruct them to seek immediate medical attention if symptoms occur.

If clinically significant hypersensitivity or anaphylaxis occur, immediately interrupt MODEYSO and initiate appropriate medical treatment and supportive care. Based on the severity of the adverse reaction, temporarily interrupt or permanently discontinue MODEYSO.

Please see Important Safety Information throughout, and full Prescribing Information.



About MODEYSO (cont.)

For patients experiencing adverse reactions with MODEYSO, **dose reductions and modifications are recommended.**¹

Recommended dosage reductions for adverse reactions¹

Patients weight (kg)	First dosage reduction	Second dosage reduction
Pediatric patients 10 kg to <12.5 kg	Permanently discontinue	N/A
Pediatric patients 12.5 kg to <27.5 kg	125 mg once weekly	Permanently discontinue
Pediatric patients 27.5 kg to <42.5 kg	250 mg once weekly	125 mg once weekly
Pediatric patients 42.5 kg to <52.5 kg	375 mg once weekly	250 mg once weekly
Pediatric patients ≥52.5 kg and adult patients	500 mg once weekly	375 mg once weekly

Recommended dosage modifications for adverse reactions¹

Adverse reaction	Severity ^a	Dosage modification
Hypersensitivity	Any grade	If hypersensitivity is suspected based on clinical judgment, interrupt MODEYSO until resolution of the event. Permanently discontinue MODEYSO in patients who develop serious hypersensitivity reactions
QT interval prolongation	QTc absolute value >500 ms or an increase of >60 ms from baseline	Interrupt MODEYSO until QTc interval ≤480 ms or return to baseline. Resume MODEYSO at the next lower dosage level
	Torsades de pointes, polymorphic ventricular tachycardia, or signs or symptoms of serious or life-threatening arrhythmia	Permanently discontinue MODEYSO
Other adverse reactions	Grade 3 or 4	Interrupt MODEYSO until ≤Grade 1 or return to baseline. Resume MODEYSO at the next lower dose level
	Recurrent Grade 4	Permanently discontinue MODEYSO

^aSeverity as defined by the National Cancer Institute CTCAE Version 5.0.¹

CTCAE=Common Terminology Criteria for Adverse Events; QTc=corrected interval from Q wave to T wave, adjusted for heart rate.

IMPORTANT SAFETY INFORMATION (CONT.)

WARNINGS AND PRECAUTIONS (CONT.)

QTc Prolongation

MODEYSO causes concentration-dependent QTc interval prolongation, which can increase the risk for ventricular tachyarrhythmias (e.g. torsades de pointes) or sudden death.

In patients who received MODEYSO and underwent at least one post baseline ECG, QTcF increase of >60 msec compared to baseline and QTcF >500 msec occurred in 6% and 1.2% of patients, respectively.

Please see Important Safety Information throughout, and full Prescribing Information.

MODEYSO Access and Affordability

MODEYSO has **broad coverage across commercial, Medicaid, and Medicare plans.**



— **APPROXIMATELY 96% OF PATIENTS** —
with commercial insurance **paid \$0 per month** with help from their insurance and with the MODEYSO copay card



JazzCares financial assistance programs can help eligible patients with commercial insurance or eligible patients who are uninsured or underinsured. See [page 6](#) to learn more.

Source: Data on File-REF-25301. Jazz Pharmaceuticals, Inc.

IMPORTANT SAFETY INFORMATION (CONT.)

WARNINGS AND PRECAUTIONS (CONT.)

QTc Prolongation

Monitor ECGs and electrolytes prior to initiation and periodically during treatment, as clinically indicated. Increase the frequency of monitoring in patients with congenital long QT syndrome, existing QTc prolongation, a history of ventricular arrhythmias, electrolyte abnormalities, heart failure, or who are taking strong or moderate CYP3A4 inhibitors.

Please see Important Safety Information throughout, and full [Prescribing Information](#).

Your Support Team



JazzCares will partner with you and Onco360® to help navigate the insurance process.

JazzCares services include:

- Completing a benefit investigation to understand your patients' coverage and out-of-pocket costs
- Helping educate on the PA process
- Assisting in understanding and supporting the appeals process if the insurance company denies coverage
- Helping determine eligibility for financial assistance programs

Onco360 services include:

- Shipping MODEYSO directly to patients
- Following up with refill reminders and additional support once the patient is on therapy and throughout their treatment journey

See page 8 for contact information.



FIELD ACCESS NAVIGATORS (FANs)

FANs provide expert understanding of regional and local access landscapes. They collaborate with you, your office, and outpatient provider care centers to offer

- Insights on payer policies
- Educational resources and reimbursement information about complex patient access issues (eg, PAs, appeals, denials, letters of medical necessity, letters of appeal)
- Expertise on Jazz's financial assistance programs for your patients
- Information on product procurement, billing, and coding

See page 8 to contact your FAN.



CARE COORDINATORS

A Care Coordinator will work with each patient to understand their unique situation and assess their eligibility for additional JazzCares support offerings.

Additionally, Care Coordinators

- Are available by phone from 8 AM to 8 PM ET, Monday through Friday
- Serve as the main point of contact for the patient
- Review eligibility for program offerings, including the Copay Assistance Program, the Quick Start Program, and the Patient Assistance Program

PA=prior authorization.

IMPORTANT SAFETY INFORMATION (CONT.)

WARNINGS AND PRECAUTIONS (CONT.)

QTc Prolongation (cont.)

Avoid concomitant use with other agents known to prolong the QT interval. If concomitant use cannot be avoided, increase the frequency of monitoring and separate administration of MODEYSO and QT-prolonging product.

Interrupt or reduce the dose of MODEYSO in patients who develop QT prolongation; permanently discontinue in patients with signs of life-threatening arrhythmias.

Please see Important Safety Information throughout, and full Prescribing Information.



Starting Patients on MODEYSO With JazzCares Support

JazzCares helps patients access their medication and offers personalized support throughout their treatment journey. Patients who enroll in JazzCares will be evaluated to determine eligibility for available financial assistance programs.

Prescribe MODEYSO

Once you decide to prescribe MODEYSO, submit the prescription to Onco360.^a

JazzCares enrollment

Complete all relevant fields on the **JazzCares Enrollment Form**, which includes a prescription for MODEYSO. If patient elects to participate, obtain required consent during the patient visit.

- Support offices with benefits verification and verifying patient coverage
- Coordinate contact with a MODEYSO Care Coordinator who will work with each patient to understand their unique situation and their eligibility for additional JazzCares support offerings

PA process and financial support programs

If a PA is required, your FAN can provide support throughout the PA process. If there is a delay in approval or a PA is denied, eligible patients may be evaluated by JazzCares for financial assistance programs, subject to program criteria.^b

- **Quick Start Program:** Patients who experience a delay in insurance approval (eg, due to PA denial), may be eligible for a **temporary no-cost supply** to help start treatment
- **Patient Assistance Program:** If PA and appeal are denied, or patients are uninsured or underinsured and meet certain eligibility and financial criteria, they **may be eligible to receive MODEYSO at no cost**

Following coverage approval, eligible patients with commercial insurance **may pay as little as \$0 OOP** for their prescription through the **Copay Assistance Program**.

See the JazzCares Patient Support Flashcard for more information.

Patient receives MODEYSO

Onco360 will deliver MODEYSO directly to the patient. JazzCares and the MODEYSO Care Coordinator can provide ongoing support to your patients.

^aSome states may require an ePrescription.

^bSubject to financial and residency eligibility criteria. Terms and conditions apply.

OOP=out-of-pocket.

IMPORTANT SAFETY INFORMATION (CONT.)

WARNINGS AND PRECAUTIONS (CONT.)

Embryo-Fetal Toxicity

MODEYSO can cause fetal harm when administered to a pregnant woman.

Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with MODEYSO and for 1 month after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with MODEYSO and for 1 month after the last dose.

Please see Important Safety Information throughout, and full Prescribing Information.

Important Safety Information

WARNINGS AND PRECAUTIONS

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QTc Interval Prolongation

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ADVERSE REACTIONS

Serious adverse reactions occurred in 33% of the 376 patients who received MODEYSO. Serious adverse reactions in >2% of patients included hydrocephalus (5%), vomiting (4.3%), headache (3.2%), seizure (2.4%), and muscular weakness (2.1%). Fatal adverse reactions occurred in 1% of patients who received MODEYSO, including cardiac arrest (0.5%), intracranial hemorrhage (0.3%), and encephalopathy (0.3%).

The most common adverse reactions ($\geq 20\%$) reported in clinical trials with MODEYSO were fatigue (34%), headache (32%), vomiting (24%), nausea (24%), and musculoskeletal pain (20%). The most common ($\geq 2\%$) Grade 3 or 4 laboratory abnormalities were decreased lymphocytes (7%), decreased calcium (2.7%), and increased alanine aminotransferase (2.4%).

DRUG INTERACTIONS

Strong and Moderate CYP3A4 Inhibitors

Avoid concomitant use of MODEYSO with strong and moderate CYP3A4 inhibitors. If concomitant use cannot be avoided, reduce the MODEYSO dose as recommended and monitor for toxicity.

Strong and Moderate CYP3A4 Inducers

Avoid concomitant use of strong and moderate CYP3A4 inducers with MODEYSO.

USE IN SPECIFIC POPULATIONS

Lactation

There are no data on the presence of MODEYSO in human milk. Because of the potential for serious adverse reactions from MODEYSO in breastfed children, advise women not to breastfeed during treatment with MODEYSO and for 1 week after the last dose.

Pediatric Use

The safety and effectiveness of MODEYSO have not been established in patients less than 1 year of age. Dosing has not been established for patients weighing less than 22 pounds (10 kg).

Please see additional Important Safety Information throughout, and full Prescribing Information.

Key Contacts



Phone: 1-844-302-2737

Hours: Monday-Friday 8 AM-8 PM ET

Website: www.jazzcares.com/hcp/modeyso

ONCO360 ONCOLOGY PHARMACY

Phone: 1-877-662-6633

Fax: 1-877-662-6355

Website: www.onco360.com

The FAN serves as the key contact for HCPs who need additional information on MODEYSO access and available support services.

IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT YOUR FAN



Jazz Pharmaceuticals

FAN name

Location

Email

Phone Number

IMPORTANT SAFETY INFORMATION (CONT.)

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Please see full Prescribing Information, including both Patient Information and Instructions for Use, for complete safety and administration information.

To learn more, visit MODEYSOhcp.com.

Reference: 1. MODEYSO™ (dordaviprone) Prescribing Information. Jazz Pharmaceuticals, Inc.

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